



2002 N-0278



May 14, 2004

**VIA FAX: 301-827-6870**

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Reopening of Comments on Interim Final Rules of  
October 10, 2003 on  
Prior Notice and Facilities Registration  
and FDA's Integration Plan with CBP  
Under the Public Health Security and Bioterrorism Preparedness  
and Response Act of 2002  
Dockets # 2002N-0278; 2002N-0276; and 2002N-0278

Gentlemen:

American Trucking Associations, Inc. (ATA), with offices at 2200 Mill Road, Alexandria, Virginia 22314-4677, is the trade association that represents the U.S. trucking industry's interests<sup>1</sup>. ATA is vitally interested in matters affecting the nation's motor carriers, including the implementation of security requirements affecting the transportation of food. For this reason, ATA and its affiliated conference, the Agricultural and Food Transporters Conference (AFTC), are submitting these comments in response to the Department of Health and Human Services' Food and Drug Administration's (FDA) Interim Final Rules (IFR) for Prior Notice and Registration of Facilities promulgated under the Bioterrorism Act of 2002 (BTA) and published in the *Federal Register* on October 10, 2003<sup>2</sup>. In addition, we are submitting comments on the FDA's proposal to integrate some of its security operations under the BTA with the Bureau of Customs and Border Protection (CBP).

<sup>1</sup> Through our affiliated trucking associations, and their over 30,000 motor carrier members, affiliated conferences, and other organizations, ATA AND AFTC represents every type and class of motor carrier.

<sup>2</sup> (68 *Federal Register* 58974 & 58894)

2002N-0278

C308

ATA and the AFTC, formerly known as the Agricultural Transporters Conference established in 1995, is the national organization representing the interests of commercial transporters of agricultural commodities and foodstuffs. Commercial agricultural transportation moves a significant percentage of all raw commodities and food either imported into the United States or transported domestically. More than 90 percent of shipments of perishables are done by truck. Food grains, liquid bulk shipments of milk, wine, and flour and other foods are transported by tank carriers. Commercial operations for transporting perishable foods are vastly different, with significantly diverse time requirements, from operations for transporting processed foods.

### **Background**

As ATA and AFTC have stated in prior comments to FDA<sup>3</sup>, the trucking industry is a critical link in the economic interdependency among the United States, Canada and Mexico, moving approximately 70 percent of the value of freight between the United States and Canada, and about 83 percent of the value of U.S.-Mexico freight<sup>4</sup>. The increasing trade volumes that have been generated among the three North American Free Trade Agreement (NAFTA) partners have not only been good for the economic well being of our countries, but also have allowed businesses throughout North America to diversify, expand, improve their asset utilization, and access new markets for their products.

According to CBP, during 2002, 6.9 million trucks entered the U.S. from Canada, while 4.4 million entered from Mexico, resulting in more than 13 million truck crossings a year on the northern border, and more than 8 million crossings on the U.S. southern border. NAFTA has generated a large increase in the amount of trade in the food, beverage and agriculture sectors throughout North America: U.S.-Canada trade in these goods increased from \$16 billion in 1997 to \$20.4 billion in 2001, while U.S.-Mexico trade for the same period increased from \$8.1 billion to \$11.6 billion.<sup>5</sup>

ATA and AFTC continue to have a number of concerns regarding FDA's IFRs, which are discussed throughout this response. Specifically, the bulk of our concerns center around the implementation and enforcement of the prior notice requirement because of the poor shipper compliance tracked by FDA so far. In addition, we offer some ideas about eliminating motor carrier facilities registrations, and tender comments on the planned integration of prior notice times under the BTA with CBP's prenotification requirements under the Trade Act of 2002.

### **Prior Notice**

The trucking industry continues to be concerned about its reliance on shipper compliance to FDA's BTA prior notice requirements. Our concerns are in two areas: 1) that we continue to go to the border with no real knowledge of whether or not a shipper has indeed filed prior notice; and 2) that we will pay the consequences for shipper noncompliance by having our

---

<sup>3</sup> American Trucking Associations; Comments to FDA Notice of Proposed Rulemaking, Published in *Federal Register* on February 3, 2003 on Registration of Food Facilities under Bioterrorism Preparedness and Response Act of 2002 (vol 68, No. 22, pp. 5378-5427); Alexandria, VA; April 4, 2003.

<sup>4</sup> Bureau of Transportation Statistics, U.S. Department of Transportation

<sup>5</sup> Trade and Economy: Data analysis, International Trade Administration, U.S. Department of Commerce, <http://www.ita.doc.gov/td/industry/otea/usftb/top80cty/top80cty.html>

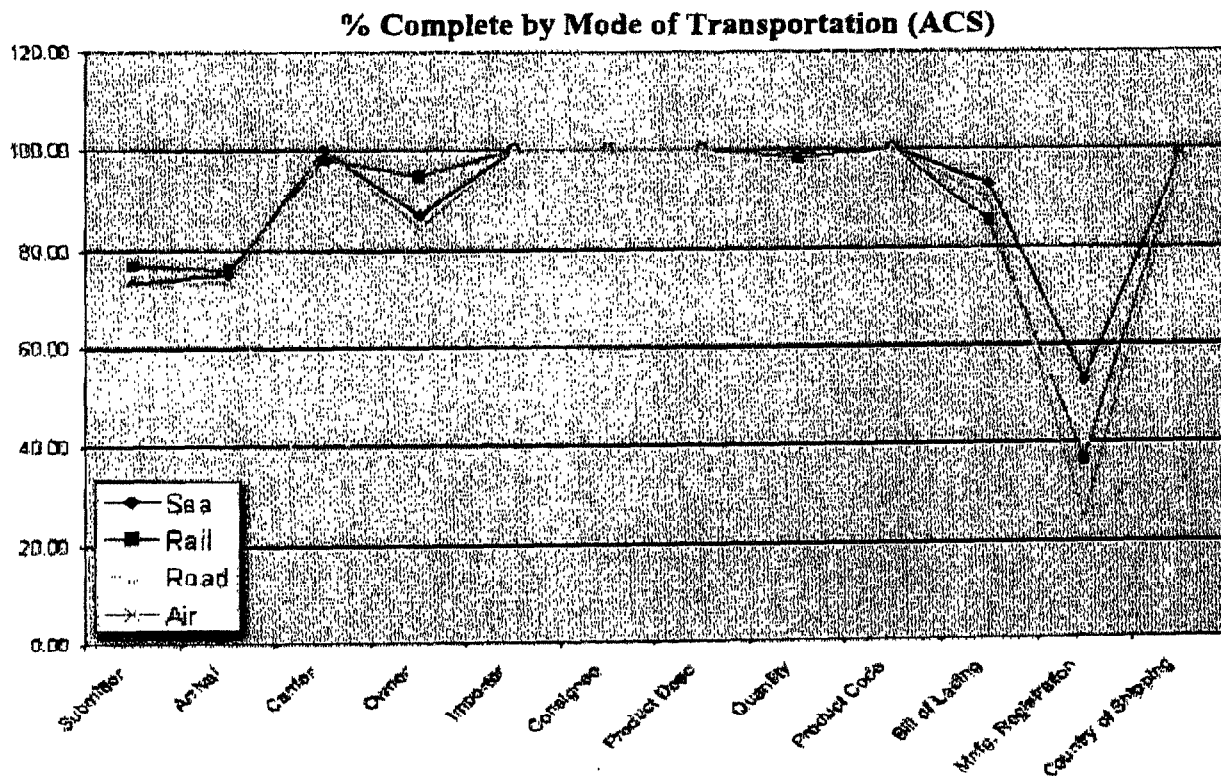
trucks detained or turned around at the borders when full enforcement begins on August 12, 2004.

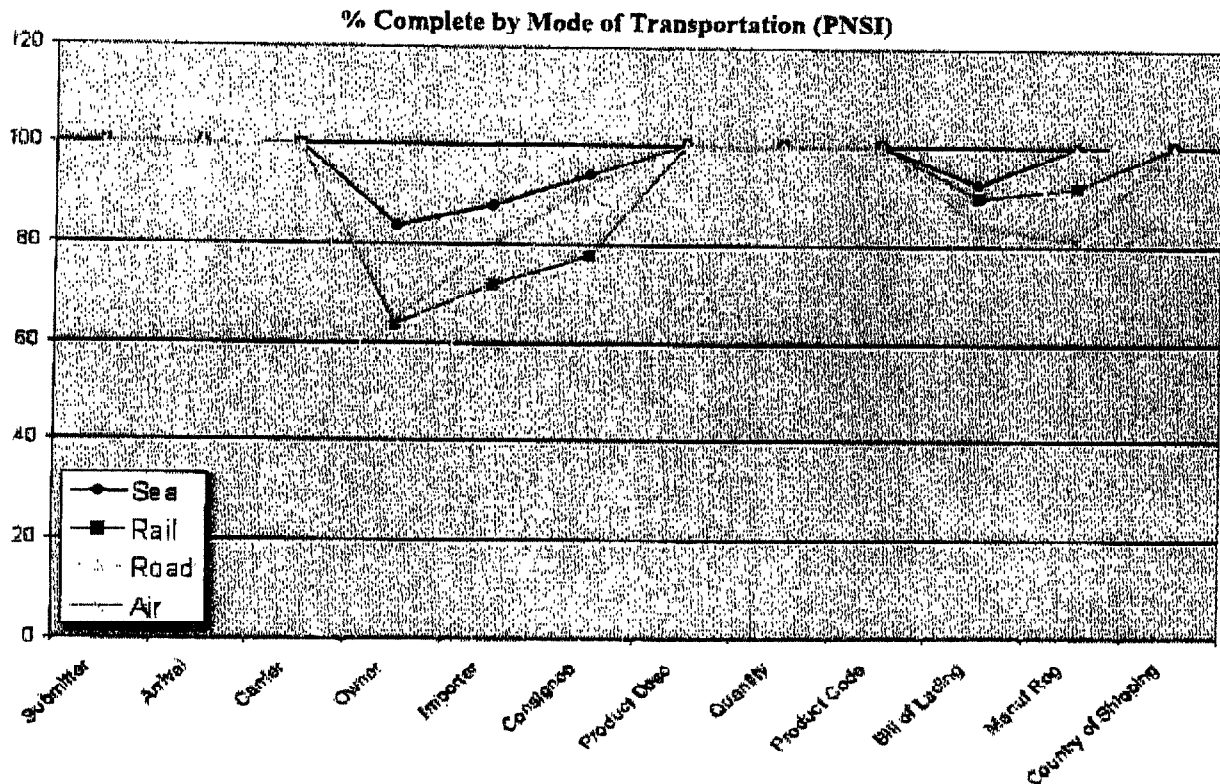
The motor carrier's potential loss of productivity from having equipment idle or inoperative when a shipment has been denied entry or is being held, is a serious negative impact on the bottom line of cross-border trucking operators. In addition, this kind of down time would have a serious negative impact on truck drivers' compensation, when they are paid based on miles driven, and greatly reduce the number of allowable hours a driver is allowed to operate under the Federal Motor Carrier Safety Regulations (FMCSR).

ATA and AFTC recognize the joint efforts that FDA and CBP have undertaken to ensure that the implementation of the Prior Notice rule does not have a negative impact on commercial trucking operations. The joint Compliance Policy Guide for FDA and CBP staff is an excellent document for assisting personnel staffing the ports of entry so that the movement of legal and safe foodstuffs is not hampered. The document does a commendable job in attempting to establish phased-in enforcement that allows the agency to educate the trade community and for CBP personnel to become better acquainted with the rule.

However, in looking at the FDA's *Compliance Summary Information: Prior Notice* report, dated April 2, 2004, which details shipper compliance with the BTA prior notice requirements, it is obvious that for trucks crossing the border with FDA-regulated goods there is a significant shipper compliance problem. We are deeply concerned about this record of shipper noncompliance, as reflected in the following graphs contained in the April 2 report:

**BTA Prior Notice Compliance by Mode**  
(Automated Commercial System Entries and PNSI Entries)





These two graphs represent the rates of compliance, through both the FDA Prior Notice System Interface (PNSI) and the Automated Commercial System (ACS), for all modes of transportation. Truck compliance is in yellow. In both graphs, compliance by shippers using trucks to move freight across the border is worst of all the transportation modes. The report concludes:

“This comparison of submissions from PNSI and ACS helps to define where efforts to increase compliance need to be concentrated. In both cases compliance for imports via land (largely trucks) generally lags behind that for other modes of transportation. Some of the differences between the systems are attributable to the current differences in edit checks between PNSI and ACS. Most of these, like Registration Number, were left open during the period of enforcement discretion to allow time for submitters to change their procedures to begin capturing and entering the required data. Others, like the low compliance rate for land carriers in ACS may indicate an area where compliance is particularly challenging, and may require further outreach and cooperation between FDA and industry to obtain full compliance.”

Based on these statements and the above figures, we urgently request that FDA dramatically escalate its efforts in the area of shipper education and compliance. Without serious intervention, on August 12, 2004, when full BTA compliance is required and hard enforcement begins, trucks will be massed at the border, unable to cross, because of shipper noncompliance with the PN requirements. This situation has the potential to provide the needed

security at our borders, but possibly dangerously minimizes the other critical border mission — i.e., trade facilitation.

Further, we suggest several steps FDA should take to protect motor carriers from paying these dire consequences when shippers fail to comply with the BTA PN requirement. To solve the shipper compliance problem, we suggest that FDA remain flexible in its plan to implement enforcement of the BTA PN requirements, by relying on the level of shipper compliance and its efforts at educating the shipper community, rather than on an inflexible predetermined plan. In addition, we request that FDA escalate its outreach to the shipper community. And, most importantly, we suggest that the agency postpone its full compliance date from August 12, 2004 to at least December 31, 2004, in order to have time to do the extensive educational outreach in the shipper community that is obviously needed in order to raise compliance rates.

#### **Failure to Notify Motor Carriers of Filing of PN**

A major concern regarding the requirement for prior notice is that motor carriers picking up FDA-regulated freight from shippers in Canada or Mexico to bring into the U.S. are not able to ascertain that the importer, shipper, or customs broker has indeed filed the appropriate prior notice. Currently, both FDA and CBP suggest that motor carriers require proof of PN filing from customers, but this type of arrangement, although “suggested,” amounts to a “pre-lading” requirement for motor carriers and is not required by law or regulation. In addition, because the FDA system’s acknowledgement of receipt of a PN does not mean that the information received is correct or complete, carriers are still left vulnerable to carrying goods that could be turned back at the border. This type of action by FDA would tie up a carrier’s equipment, negatively affect driver wages, and have a serious effect on carrier productivity.

In the LTL environment, where on average a trailer contains about 40 shipments, when a single shipment is not filed in a timely fashion and is held at the border, this has potentially serious impacts on a number of parties. Holding an LTL trailer at a port of entry or turning the entire load around because of insufficient PN filing would affect not only the motor carrier’s operations, but also all of the shippers, importers, and consignees whose goods are on board.

#### **Plan to Integrate BTA Prior Notice Requirements with CBP Prenotification under Trade Act of 2002**

ATA and AFTC support the concept of inter-governmental agency cooperation and dependence. We believe that the executive branch also does, with, for example, the E-Government initiative that links 26 agencies human resource functions for 1.8 million government workers, into one database. In that vein, we fully support FDA’s willingness to cooperate and become interdependent with CBP in order to screen imported food goods.

Specifically, ATA and AFTC believe there are three specific areas where FDA could benefit by working closely with CBP:

1. **Import System Integration:** ATA and AFTC congratulate FDA for coordinating with CBP to allow transmission of FDA-required information through the Automated Broker Interface (ABI) to CBP’s Automated Customs System (ACS). In addition, we support the integration and cooperation of both agencies in utilizing CBP’s Automated Targeting System to efficiently and rapidly spot anomalies in freight crossing our borders.

2. Supply Chain Security: ATA and AFTC would support FDA's utilization of the benefits of associating with CBP's Customs Trade Partnership Against Terrorism (C-TPAT) and the Free and Secure Trade (FAST) programs. When undertaking risk assessments on imported foods transported by participating motor carriers, ATA and AFTC support the concept of FDA providing special treatment to those accepted into these programs.
3. Prior Notice Timeframes: Both ATA and AFTC support the coordination of FDA Prior Notice requirements under the BTA with CBP's prenotification requirements under the Trade Act of 2002. For freight to qualify as C-TPAT, both the motor carrier and the importer of record must be enrolled in the C-TPAT program.
4. International Trade Data System (ITDS): ATA and AFTC support the utilization of ITDS, which provides for one-window filing of trade-related information by motor carriers and other parties through CBP's ACE system. Considering the immense benefits that ITDS offers by its instantaneous and complete passage of critical trade information to government agencies, FDA should participate in this system sooner rather than later in order to more effectively execute its Bioterrorism Act mission.

### **Registration of Facilities**

ATA and AFTC note that the original FDA requirement for the trucking industry under the BTA proposed regulations was to have trucking companies and truck terminals register as holders of food. Despite our numerous objections to this requirement, on December 12, 2003, as dictated under the BTA registration of facility regulations, thousands of trucking companies completed their registrations, incurring substantial costs in man hours industry-wide. On or around December 29, 2003, FDA reversed this registration requirement for trucking companies and truck terminals, stating that it would no longer require these entities to register as holders of food. As welcome as this decision was, it would have been infinitely better had the agency heeded the voices of the trucking industry when industry objections were initially raised.

In the meantime, we strongly suggest that the agency, not the carriers, cancel these truck terminal registrations. It is impracticable to expect the motor carrier industry to shoulder an additional financial and manpower burden to correct the agency's error in judgment.

### **Conclusion**

ATA, the AFTC and the trucking industry share the FDA's and our entire nation's concern for securing our national and economic security. In addition to reactive measures our industry has taken to comply and work with various proposals by Congress and regulatory agencies, the trucking industry has also initiated a number of proactive measures regarding the security of our operations after, and even well before, the terrorist attacks of September 11.

For many years, motor carriers have faced the challenge posed by organized groups involved in cargo theft. After September 11, ATA expanded our industry's efforts to ensure that a commercial vehicle not be used to transport a weapon of mass destruction or that it be used as a weapon itself. This effort resulted in the creation of an American trucking industry Anti-Terrorism Action Plan (ATAP). ATAP has allowed trucking industry representatives to present a solid front to stem the possibility of a terrorist attack on our transportation industry and infrastructure. ATA has closely coordinated many of ATAP's principal initiatives with state and federal government agencies to help monitor our transportation modes and our

nation's highways. Currently, the AFTC is working under a contract with the U.S. Department of Agriculture to create a *Guide for Security Practices in the Transportation of Agricultural Commodities*.

In addition to coordinating with various segments of the transportation industry, ATA and AFTC also interact with a large number of government agencies developing separate security initiatives that could have an impact on trucking operations. ATA and AFTC believe it is essential that all agencies planning or developing security initiatives impacting international trade coordinate closely with agencies within DHS, such as CBP and the Transportation Security Administration (TSA) in order to avoid duplication of efforts and programs.

In summary, ATA and AFTC urge that the following issues be taken into consideration by FDA when reconsidering the IFRs:

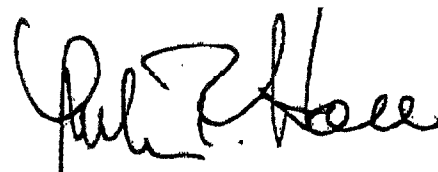
- Concentrate on doing more outreach to the shipping community for increased BTA prior notice compliance
- Re-tool the 3-stage enforcement plan for BTA prior notice requirement, linking enforcement with levels of successful education and compliance measurements
- Extend the PN full compliance deadline date from August 12 to at least December 31, 2004, depending on shipper compliance rates
- Coordinate BTA PN time requirements with CBP's Trade Act prenotification times for all modes of transportation
- Consider further cooperation and integration with CBP systems and procedures for more efficiency at the borders, to include FAST and C-TPAT
- Escalate the agency's process to participate in ITDS
- Cancel motor carrier facilities registrations system wide

ATA and AFTC appreciate the opportunity to comment on these important issues relative to the Interim Final Rules, and we look forward to working with FDA and other government agencies in ensuring our national and economic security. If you have any questions related to these comments, please call Margaret Irwin at (703) 838-1745 or Fletcher Hall at (703) 838-7999.

Sincerely,



Margaret Irwin  
Director  
Customs, Immigration &  
Cross-Border Operations



Fletcher R. Hall  
Executive Director  
Agricultural & Food Transporters  
Conference

2200 Mill Road, Alexandria, VA 22314  
Telephone: 703-838-1745, FAX: 703-549-9570

## American Trucking Associations

# Fax

**To:** Dockets Branch

**From:** Margaret Irwin, Director

Customs, Immigration & Cross-Border

**Fax:** 301-827-6870

**Pages:** 8, including cover sheet

**Phone:**

**Date:** 5/14/2004

**Re:** Comments 2002N-0278, 2002N-0276

**CC:**

☐ **Urgent**    ☐ **For Review**    ☐ **Please Comment**    ☐ **Please Reply**    ☐ **Please Recycle**

• **Dockets Branch:** Because the electronic docket was unable to accept filing of this document, I am forwarding it to you via fax. Please note that the charts on pages 3 and 4 of this document are in color. To receive a copy of the document in color, please contact Cathy Durfey at 703-838-1996.

If you have any questions about this filing, please contact me at 703-838-1745.

Thank you.